



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/568,071

04/05/2006

Maria Gabriella Santoro

2520-1073

7454

466 7590 10/09/2009

YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
ALEXANDRIA, VA 22314

EXAMINER

ZAREK, PAUL E

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

10/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,071	<b>Applicant(s)</b> SANTORO, MARIA GABRIELLA	
	<b>Examiner</b> Paul Zarek	<b>Art Unit</b> 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 54-78 is/are pending in the application.
- 4a) Of the above claim(s) 54-64, 67, 71 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65, 66, 68-70 and 73-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/13/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1617

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 54, 55, 57, 58, 64, 65, 66, 68-70, and 75-78 have been amended by the Applicant in correspondence filed on 08/19/2009. Claims 54-78 are currently pending. Claims 54-64, 67, 71, and 72 remain withdrawn for being drawn to a nonelected species or invention. Claims 65, 66, 68-70, and 73-78 are examined herein. This is the second Office Action on the merits of the claim(s).

## **RESPONSE TO ARGUMENTS**

2. Examiner acknowledges receipt of foreign patent and non-patent literature documents disclosed in IDS filed on 02/13/2006. Examiner has considered the contents of said documents.

3. Claims 65 and 75 were objected to because “INDO” and “BBB” were not defined in the claims. These objections are moot in light of Applicant’s amendment to Claims 65 and 75.

4. Claim 76 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is moot in light of Applicant’s amendment to Claim 76.

5. Claims 65, 66, 68-70, and 73-78 were rejected under 35 U.S.C. 112, second paragraph, because “derivative” was considered indefinite. This rejection is moot in light of Applicant’s amendment to the claims.

6. Claims 65, 66, 68, 73, 74, and 77 were rejected under 35 U.S.C. 102(b) as being anticipated by Regtop and Biffin (US Patent No. 5,466,824, issued 1995). Applicant traversed

Art Unit: 1617

this rejection on the grounds that Regtop and Biffin did not anticipate the claims. Specifically, Applicant asserts that Regtop and Biffin teach a composition in which a metal and indomethacin form a complex. Applicant further asserts that Regtop and Biffin require a divalent metal and prefers cupric acetate rather than the metals claimed in instant Claims 66 and 68. Applicant notes that gold, bismuth and selenium are not divalent metals. Applicant states that the instant invention is a composition of indomethacin and a metal which “are not intended to form a complex with each other”. Respectfully, Examiner does not find Applicant’s arguments persuasive.

7. Regtop and Biffin teach a composition comprising a metal or metal salt and indomethacin. There is no limitation in the instant claims requiring the indomethacin and metal or metal salt to be non-complexed. Moreover, Regtop and Biffin specifically contemplate zinc, which is a divalent metal. Regardless that this prior art exemplifies only cupric acetate, it still specifies zinc as a preferred divalent metal. Therefore, the rejection of Claims 65, 66, 68, 73, 74, and 77 under 35 U.S.C. 102(b) as being anticipated by Regtop and Biffin is maintained.

8. Claims 69 and 70 were rejected under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin (above) in view of Berge, et al. (Journal of Pharmaceutical Sciences, 1977). Applicant traversed this rejection for the alleged weakness of Regtop and Biffin. Regtop and Biffin disclose a composition comprising indomethacin and a metal salt (see above), and thus read on Claims 69 and 70. Applicant has not disagreed with Berge in the capacity with which it was applied. Therefore, the rejection of Claims 69 and 70 under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin in view of Berge, et al., is maintained.

Art Unit: 1617

9. Claim 75 was rejected under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin (above) in view of Wilkinson (Goodman & Gilman's The Pharmaceutical Basis of Therapeutics 10<sup>th</sup> ed., Chapter 1: Pharmacokinetics, 2001). Applicant traversed this rejection for the alleged weakness of Regtop and Biffin. Regtop and Biffin disclose a composition comprising indomethacin and a metal salt (see above), and thus read on Claim 75. Applicant has not disagreed with Wilkinson in the capacity with which it was applied. Therefore, the rejection of Claim 75 under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin in view of Wilkinson is maintained.

10. Claim 76 was rejected under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin (above) in view of Engler, et al. (US Patent No. 6,165,779, issued 2000). This rejection is moot in light of Applicant's amendment to Claim 76.

11. Claim 78 was rejected under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin (above) in view of Taylor, et al. (US Patent No. 6,303,295, issued 2001). Applicant traversed this rejection for the alleged weakness of Regtop and Biffin. Regtop and Biffin disclose a composition comprising indomethacin and a metal salt (see above). Applicant further asserts that Taylor, et al., fails to teach that a composition comprising selenium and indomethacin could be useful for the treatment of various diseases, such as SARS or hemorrhagic fevers. Thus, Applicant contends, there is no motivation to combine selenium with indomethacin. Respectfully, Examiner does not find Applicant's arguments persuasive.

12. Regtop and Biffin teach an indomethacin and metal salt composition but do not teach a composition to comprise specifically gold, selenium, or bismuth. Taylor, et al., teach the importance of dietary selenium for proper immune function (col 1, lines 50-57). Since it is

Art Unit: 1617

known that indomethacin and selenium possess antiviral faculties, it would have been obvious to combine them in a single formulation. (*In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (MPEP § 2144.06(I)) One of ordinary skill in the art would be motivated to combine indomethacin and selenium because both were known to be effective anti-viral drugs. Therefore, the rejection of Claim 78 under 35 U.S.C. 103(a) as being unpatentable over Regtop and Biffin in view of Taylor, et al., is maintained.

13. Amended Claim 76 is examined on their merits and the following **FINAL** rejection is made.

***Claim Rejections - 35 USC § 102***

14. The text of Title 35, U.S.C. § 102(b) can be found in a prior Office action.

15. Claim 76 is rejected under 35 U.S.C. 102(b) as being anticipated by Regtop and Biffin (above).

16. Amended Claim 76 is drawn to a composition comprising indomethacin and/or a salt thereof in combination with Interferon, metals and corresponding salts, prostanoids, and/or antiviral drugs; and a pharmaceutically acceptable carrier.

17. Regtop and Biffin were described above and in Office Action mailed on 01/14/2009. Briefly, Regtop and Biffin teach a composition comprising indomethacin and a divalent metal together with a pharmaceutically acceptable carrier, diluent and/or excipient (abstract). Therefore, Regtop and Biffin anticipate all the limitations of the rejected claim.

Art Unit: 1617

***Conclusion***

18. Claims 65, 66, 68-70, 73-75, 77, and 78 remain rejected. Newly amended Claim 76 is rejected.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brendon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/  
Primary Examiner, Art Unit 1628